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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,482	09/09/2003	Daryl T. Baldwin	P1974R1	3368

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,482	BALDWIN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005 and 06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/15/03, 12/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-30 are pending in the instant application.

Applicant's election without traverse of Group I, claims 1-8, drawn to polynucleotides, vectors and host cells encompassing SEQ ID NO:1, in the reply filed on September 26, 2005 is acknowledged.

Claims 9-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in the reply filed on September 26, 2005.

Claims 1-8 are under examination as they read on polynucleotides, vectors, host cells and methods of using host cells to produce polypeptides that comprise SEQ ID NO:1.

Applicant is thanked for the amendments to the specification to include a sequence listing in the reply received January 6, 2006. It is requested that applicant amend the first line of the specification to indicate that the instant application claims priority to US provisional application 60/410,062 filed September 11, 2002.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

2. Applicant's IDS forms received 12/15/03 and 12/28/04 have been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid of SEQ ID NO:1 as well as vectors, host cells, and methods of using host cells that contain SEQ ID NO:1 , does not reasonably provide enablement for isolated nucleic acids 80% identical to SEQ ID NO:1 as well as vectors, host cells, and methods of using host cells that contain sequences 80% identical to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
Applicant has claimed the genus of polynucleotides, vectors and host cells that are 80% or more identical to SEQ ID NO:1, and has disclosed that SEQ ID NO:1 encodes the

polypeptide of SEQ ID NO:2. The specification discloses that increased expression of the polynucleotide of SEQ ID NO:1 can be detected in patients suffering from psoriasis and inflammatory bowel disease as compared to healthy controls (see particularly Examples 3 and 4) The specification does not appear to teach the function of the polynucleotide of SEQ ID NO:1 or its encoded polypeptide SEQ ID NO:2. No working examples of polynucleotides 80% or more identical to SEQ ID NO:1 appear to be present in the instant specification, and no guidance concerning which bases within the sequence of SEQ ID NO:1 are important for maintenance of the function of SEQ ID NO:1 and therefore must be maintained in polynucleotides 80% or more identical to SEQ ID NO:1, or conversely which bases are not relevant and can be changed at will, appears to be disclosed. Such guidance is critically important because as has already been discussed, the specification does not appear to provide data and clear teachings concerning the biological function(s) of the polynucleotide of SEQ ID NO:1. Note that demonstration that a particular sequence is upregulated in a particular disease or condition and thus can serve as a marker for the presence of that disease or condition does not provide evidence that the sequence is causative of the disease/condition and as such modulating the sequence would have therapeutic utility (Blalock et al., Ageing Research Reviews, 2005, 4:481-512, see entire document, particularly the abstract, the paragraph that spans pages 482 and 483.

Skolnick et al. (Trends in Biotechnology, 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the

multifunctional nature of proteins (see entire document, particularly the Abstract and the section titled Sequence-based approaches to function prediction on page 34). Even in situations where there is some confidence of a similar overall structure between two sequences, only experimental research can confirm the artisan's best guess as to the function of the structurally related sequence (see in particular the Abstract and Box 2 on page 36). The complexity of the problem of assigning function based on homology rises as the percent similarity or identity falls (see Whisstock et al., Quarterly Reviews of Biophysics, 2003, 36:307-340, particularly the sentence that spans pages 321 and 323). Given that neither the specification nor the prior art clearly indicate the structural region(s) the polynucleotide of SEQ ID NO:1 that are essential for maintenance of the biological function of SEQ ID NO:1, whatever that biological function may be, a skilled artisan would not expect any sequence sharing less that 100% identity with SEQ ID NO:1 to share the functional activities of SEQ ID NO:1. As such, a skilled artisan would be unable to make and use the full breadth of applicant's claimed polynucleotide sequences, as well as the vectors and host cells comprising such polynucleotides, without first conducting additional research.

5. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an isolated polynucleotide comprising SEQ ID NO:1, as well as vectors and host cells that comprise SEQ ID NO:1.

Applicant is not in possession of isolated polynucleotide sequences, vectors, and host cells that comprise polynucleotides that are 80% or more identical to SEQ ID NO:1.

Applicant has broadly claimed polypeptide sequences that share 80% or greater identity with SEQ ID NO:1. SEQ ID NO:1 is 831 base pairs in length, so a polynucleotide sequence at least 80% identical to SEQ ID NO:1 allows for 166 nucleotides to be mismatched (831 x 20%). Therefore, this genus minimally contains at least 166^4, or 759,333,136 sequences, with the real number being even larger since the precise number and location of the mismatches can vary. To support this genus, applicant has provided the sequence of SEQ ID NO:1.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Skolnick et al. (Trends in Biotechnology, 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see entire document, particularly the Abstract and the section titled Sequence-based approaches to function prediction on page 34). Even in situations where there is some confidence of a similar overall structure between two sequences, only experimental research can confirm the artisan's best guess as to the function of the structurally related sequence (see in particular the Abstract and Box 2 on page 36). The complexity of the problem of assigning function based on homology rises as the percent similarity or identity falls (see Whisstock et al., Quarterly Reviews of Biophysics, 2003, 36:307-340, particularly the sentence that spans pages 321 and 323).

No functional limitations are required of sequences that share 80% or more identity to SEQ ID NO:1, and the regions of these polynucleotides that are critical for function and must be maintained are not defined by the specification, nor are regions that can be successfully modified without influencing function defined. Indeed, the function of SEQ ID NO:1 itself does not appear to be disclosed other than that it can be used as a marker to identify patients suffering form psoriasis and inflammatory bowel disease. In light of this, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of polynucleotide sequences that are less than 100% identical to SEQ ID NO:1, and thus applicant was not in possession of the claimed genus of all polynucleotide sequences that are 80% or more identical with SEQ ID NO:1. Applicant is directed to the

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. Before setting forth the art rejections, it is noted that claims 1, 2, and their dependent claims recite the limitation of a nucleic acid "having" some identity to a particular sequence. The term "having" has been interpreted by the examiner to indicate open sequence language equivalent to the conventionally used term "comprising" such that the claimed nucleic acid can have additional sequence present at one or both ends of the sequence. It is suggested that applicant amend the claims to replace the term "having" with comprising if this is the breadth applicant intends by the recitation of this term. If applicant feels that the examiner has misinterpreted the true scope of the instant claims, applicant should specifically point out the true scope of the claims in response to this office action.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al. (WO 00/58334, of record as document 8 on the IDS received 12/28/04, see entire document).

Rosen et al. teach a polynucleotide sequence that is greater than 80% identical to SEQ ID NO:1 of the instant invention and its use in vectors, host cells, and methods for producing polypeptides using host cells (see entire document, particularly the abstract, page 25, page 61, pages 64-69, pages 113-117, pages 129-132, and the enclosed sequence alignment between SEQ ID NO:1 of the instant invention and SEQ ID NO:33 of Rosen et al.). Host cells transfected with the vectors disclosed by Rosen et al. include *E. coli*, *S. cerevisiae*, and CHO cells (see particularly the paragraph that spans pages 129 and 130). Note that the polynucleotide of SEQ ID NO:1 encodes the polypeptide of SEQ ID NO:2.

Therefore, the prior art anticipates the claimed invention.

9. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Lehr-Mason et al. (WO 03/068943, see entire document).

Lehr-Mason et al. teach a polynucleotide that is 100% identical to SEQ ID NO:1 of the instant application (see entire document, particularly the abstract and the provided sequence alignment between SEQ ID NO:1of the instant invention and SEQ ID NO:95 of Lehr-Mason et al.). Vectors comprising the nucleic acid of Lehr-Mason et

al., as well as host cells and methods of producing polypeptides using host cells are also disclosed (see particularly pages 53-59 and Example I beginning on page 88). Specific host cells transfected with the vectors disclosed by Lehr-Mason et al. include *E. coli*, *S. cerevisiae*, and CHO cells (see particularly line 32 of page 54, line 12 of page 55 and line 11 of page 58). Note that the polynucleotide of SEQ ID NO:1 encodes the polypeptide of SEQ ID NO:2.

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehr-Mason et al. (WO 03/068943, see entire document).

Lehr-Mason et al. teach a nucleic acid that encodes a polypeptide, wherein the sequences of both the polynucleotide and polypeptide are 100% identical to SEQ ID

NO:1 and SEQ ID NO:2 of the instant specification (see entire document and the enclosed alignments between applicant's SEQ ID NO:1 and SEQ ID NO:95 of Lehr-Mason et al. and between applicant's SEQ ID NO:2 and SEQ ID NO:44 of Lehr-Mason et al.). It is noted that the polypeptide sequence disclosed by Lehr-Mason et al. is larger than SEQ ID NO:2 of the instant invention, and that the scope of claim 3 is limited to a nucleic acid that encodes only the amino acid coding region of SEQ ID NO:1 due to the recitation of the closed sequence language "consisting of" and the fact that SEQ ID NO:1 encodes SEQ ID NO:2. Lehr-Mason et al. also teach that polypeptides can begin at any methionine residue within their disclosed polypeptide sequence (i.e., they disclose a genus of peptides that are subsequences of SEQ ID NO:44 of Lehr-Mason et al. wherein all members of the genus have a methionine as the first amino acid, see particularly lines 2-4 of page 91). Polynucleotides derived from the nucleic acid sequences disclosed by Lehr-Mason et al. include fragments of the disclosed sequences, and such shorter sequences have the advantage of being suitable for use in microarrays (see particularly lines 10-20 of page 83). Other advantages of polynucleotides that encode polypeptides that begin at a methionine residue internal to the polypeptide sequences disclosed by Lehr-Mason et al. is that such polynucleotides are taught for use in producing polypeptides useful in making and screening for compounds that specifically bind said polypeptides, such as in methods of making antibodies (see particularly lines 4-32 of page 59).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to make polynucleotides consisting of the coding sequence

of SEQ ID NO:1 (i.e. that encode SEQ ID NO:2) since Lehr-Mason et al. teach a polynucleotide that encodes a longer polypeptide that completely contains SEQ ID NO:2 of the instant invention, teach that their disclosed polypeptides start at any internal methionine and teach that such smaller polypeptides and the polynucleotides encoding them can be advantageously used to make microarrays and antibodies that be used in diagnostic and therapeutic applications. Note that a cDNA beginning at an internal methionine codon of SEQ ID NO:95 of Lehr-Mason would consist of the protein coding region of SEQ ID NO:1 (i.e. would encode SEQ ID NO:2).

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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